

INTERNATIONAL COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 04 April 2001 (04.04.01)	
International application No. PCT/EP00/06792	Applicant's or agent's file reference SANSYL001/MB
International filing date (day/month/year) 27 June 2000 (27.06.00)	Priority date (day/month/year) 28 June 1999 (28.06.99)
Applicant AL AUX, Gérard et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 25 January 2001 (25.01.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Juan Cruz Telephone No.: (41-22) 338.83.38
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

14

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SANSYL001/MB		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP00/06792	International filing date (day/month/year) 27/06/2000	Priority date (day/month/year) 28/06/1999	
International Patent Classification (IPC) or national classification and IPC A61K9/50			
Applicant SANOFI-SYNTHELABO			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 25/01/2001	Date of completion of this report 18.09.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Hedegaard, A Telephone No. +49 89 2399 8644



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/06792

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-19 as originally filed

Claims, No.:

9-14,22 (part), as originally filed
23-26

1-8,15-21, with telefax of 05/09/2001
22 (part)

Drawings, sheets:

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/06792

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-26
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-26
Industrial applicability (IA)	Yes:	Claims	1-26
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Reasoned Statement V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: WO-A-96/41617

D2: EP-A-0 908 177

D1 discloses (see the abstract and claims 1 and 6) pharmaceutical compositions comprising an active ingredient (e.g. sleep-inducing and tranquillising substances such as diazepam) with release of the latter at successive times and at different rates, comprising a first fraction for **immediate** release and a second fraction for **delayed/modulated/slow** release. In claims 26 and 32 of D1 double-layered tablets and capsules comprising two different granulates (one granulate for immediate release and one granulate for delayed and programmed release) are disclosed.

D2 discloses (see claim 1) pharmaceutical compositions comprising bromazepam having a first fraction for quick release and a second fraction for slow release.

2. The subject-matter of claim 1 is not considered novel (Art. 33(2) PCT) over D1 and D2, each document taken separately (see above under item 1).

It is here pointed out that the documents D1 and D2 do not mention a timed dual release in which the release rate is zero or is very low during a fixed time and then the whole of the drug comprised in the dosage form is released rapidly as in the present application. However, the terms "immediate", "delayed" and "fixed time" in claim 1 are so vague and unclear that a clear distinction over D1 and D2 is not possible. In present claim 1 it appears necessary to define the dual release more exactly to obtain a clear distinction over D1 and D2; e.g. by specifying the "immediate release", the "fixed time" and the "delayed release pulse" as in dependent claims 2, 3 and 6.

3. Claims, that are not novel, cannot involve an inventive step (Art. 33(3) PCT).

However, it appears that if the applicant overcomes the above-mentioned novelty objection, then an inventive step can be acknowledged since D1 and D2 mainly relate to a combination of an immediate release and a sustained release over a prolonged time whereas the present application relates to obtaining two specific release pulses, the first being immediate (lasting up to 30 minutes) and the second release only after a fixed time (between 50 and 200 minutes) and being rapid (between 30 and 200 minutes).

4. A positive international preliminary examination report for the subject-matter of the dependent claims 2-26 can only be established when they refer to an independent claim which meets the requirements of the PCT.

Re Section VII

Certain defects in the international application

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.

Re Section VIII

Certain observations on the international application

1. The term "short-acting" used in claims 1 and 8 is vague and unclear and leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject-matter of said claims unclear (Article 6 PCT).

It is pointed out that no proof has been provided that the hypnotic "bromazepam" according to D2 is not short-acting.

**REPLACED BY
ART 34 AMDT**

15. A pharmaceutical composition according to any one of claims 10 to 13, characterised in that the delayed release particles or tablets are coated with a mixture containing at least one ammonio methacrylate copolymer and the core contains a zwitterionic surfactant.

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16. A pharmaceutical composition according to claim 14, characterised in that the cationic surfactant is chosen among trimethyl-dimyristoyl-ammonium propionate, dimethyl-dioctadecyl-ammonium bromide, trimethyl-cetyl-ammonium bromide, dimethyl-didodecyl-ammonium bromide, benzalkonium chloride, cetylpyridinium chloride and cetrimide.

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17. A pharmaceutical composition according to claim 15, characterised in that the zwitterionic surfactants are chosen among N-alkylbetaines, C-alkylbetaines, N-alkylamidobetaines, N-alkylglycines, phosphatidylcholines and lecithines.

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18. A pharmaceutical composition according to claim 16, characterised in that the zwitterionic surfactant is cocamidopropylbetain.

19. A pharmaceutical composition according to claim 8, characterised in that the immediate release entity and the prolonged release entity are administered simultaneously but separately.

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20. A pharmaceutical composition according to anyone of claims 1 to 18, characterised in that the prolonged release entity comprises a pharmaceutical acceptable organic acid which can be chosen among tartaric, malic, fumaric, lactic, citric, adipic or succinic acid and their acid salts, in the form of racemates or isomers.

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21. A pharmaceutical composition according to any one of claims 1 to 20, characterised in that the short acting hypnotic belongs to the therapeutic classes of benzodiazepines, cyclopyrrolones, pyrazolopyrimidines, phenothiazines or imidazopyridines.

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22. A pharmaceutical composition according to claim 21, characterised in that the short acting hypnotic is chosen among triazolam, temazepam, brotizolam,

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Claims

1. A pharmaceutical composition comprising a short acting hypnotic or a salt thereof characterised in that it consists of a timed dual release dosage form adapted to release the short acting hypnotic over a predetermined time period, according to an *in vitro* profile of dissolution when measured in a rotating paddle apparatus of the European pharmacopoeia in aqueous buffer at 37°C, comprising two release pulses, the first being immediate and the second being delayed by a fixed time after the administration.
2. A pharmaceutical composition according to claim 1, characterised in that the first pulse has a maximum duration of 30 minutes.
3. A pharmaceutical composition according to claim 1 or 2, characterised in that the fixed time is between 50 and 200 minutes.
4. A pharmaceutical composition according to claim 3, characterised in that the fixed time is between 60 and 150 minutes.
5. A pharmaceutical composition according to any one of claims 1 to 4, characterised in that 40 to 70% of the total amount of the short acting hypnotic is released during the immediate release pulse.
6. A pharmaceutical composition according to any one of claims 1 to 5, characterised in that the delayed release pulse lasts between 30 and 200 minutes.
7. A pharmaceutical composition according to any one of claims 1 to 6, characterised in that the time for release of 85% of the total amount of the short acting hypnotic is between 2 and 6 hours.
8. A pharmaceutical composition comprising a short acting hypnotic or a salt thereof characterised in that it comprises two kinds of pharmaceutical entities: one immediate release entity and one delayed release entity.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
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(10) International Publication Number
WO 01/00181 A3

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(21) International Application Number: PCT/EP00/06792

(22) International Filing Date: 27 June 2000 (27.06.2000)

(25) Filing Language: English

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99401605.3 28 June 1999 (28.06.1999) EP

(71) Applicant (for all designated States except US):
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(72) Inventors; and

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(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ,
DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR,
HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR,
LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ,
NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM,
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(84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian
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patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
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CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

- With international search report.
- Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.

(88) Date of publication of the international search report:
1 March 2001

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: TIMED DUAL RELEASE DOSAGE FORMS COMPRISING A SHORT ACTING HYPNOTIC OR A SALT THEREOF

(57) Abstract: The present invention relates to timed dual release dosage forms of short acting hypnotics or salts thereof adapted to release the short acting hypnotic over a predetermined time period, according to a profile of dissolution characterised in that it comprises two release pulses, the first being immediate (lasting up to 30 minutes) and the second being delayed by a fixed time (this fixed time being between 50 and 200 minutes).

WO 01/00181 A3

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 00/06792

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/50 A61K9/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, EPO-Internal, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 41617 A (APPLIED PHARMA RESEARCH) 27 December 1996 (1996-12-27) figure 4 claims 1,2,6,26,30-33 ---	8-13,19, 21
X	EP 0 908 177 A (GOLD, OSCAR) 14 April 1999 (1999-04-14) claims 1,17,21 ---	8-13,19, 21
A	WO 97 23219 A (ETHYPHARM) 3 July 1997 (1997-07-03) the whole document ---	1-26
A	GB 2 185 887 A (FARMITALIA) 5 August 1987 (1987-08-05) the whole document ---	1-26
-/--		

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *8* document member of the same patent family

Date of the actual completion of the international search

11 December 2000

Date of mailing of the international search report

18/12/2000

Name and mailing address of the ISA

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NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl.
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Authorized officer

Ventura Amat, A

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 00/06792

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR 2 656 303 A (PARKE-DAVIS) 28 June 1991 (1991-06-28) the whole document -----	1-26

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 00/06792

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9641617 A	27-12-1996	IT MI951223 A CA 2224267 A EP 0833618 A	09-12-1996 27-12-1996 08-04-1998
EP 908177 A	14-04-1999	BR 9802915 A	11-01-2000
WO 9723219 A	03-07-1997	FR 2742660 A AU 721949 B AU 1198397 A BG 102555 A BR 9612225 A CA 2242224 A CN 1207681 A EP 0868184 A HU 9904129 A JP 2000506500 T NO 982738 A PL 327567 A	27-06-1997 20-07-2000 17-07-1997 26-02-1999 13-07-1999 03-07-1997 10-02-1999 07-10-1998 28-04-2000 30-05-2000 21-08-1998 21-12-1998
GB 2185887 A	05-08-1987	DE 3705074 A CH 671881 A	01-09-1988 13-10-1989
FR 2656303 A	28-06-1991	NONE	

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference SANSYL001/MB	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/EP 00/ 06792	International filing date (day/month/year) 27/06/2000	(Earliest) Priority Date (day/month/year) 28/06/1999
Applicant SANOFI-SYNTHELABO		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PC 00/06792

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/50 A61K9/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, EPO-Internal, CHEM ABS Data

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X	WO 96 41617 A (APPLIED PHARMA RESEARCH) 27 December 1996 (1996-12-27) figure 4 claims 1,2,6,26,30-33 ----	8-13, 19, 21
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A	WO 97 23219 A (ETHYPHARM) 3 July 1997 (1997-07-03) the whole document ----	1-26
A	GB 2 185 887 A (FARMITALIA) 5 August 1987 (1987-08-05) the whole document ----	1-26
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- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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- *G* document member of the same patent family

Date of the actual completion of the international search

11 December 2000

Date of mailing of the international search report

18/12/2000

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/JP 00/06792

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>FR 2 656 303 A (PARKE-DAVIS) 28 June 1991 (1991-06-28) the whole document</p> <p>-----</p>	1-26

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/JP 00/06792

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9641617	A	27-12-1996	IT MI951223 A	09-12-1996
			CA 2224267 A	27-12-1996
			EP 0833618 A	08-04-1998
EP 908177	A	14-04-1999	BR 9802915 A	11-01-2000
WO 9723219	A	03-07-1997	FR 2742660 A	27-06-1997
			AU 721949 B	20-07-2000
			AU 1198397 A	17-07-1997
			BG 102555 A	26-02-1999
			BR 9612225 A	13-07-1999
			CA 2242224 A	03-07-1997
			CN 1207681 A	10-02-1999
			EP 0868184 A	07-10-1998
			HU 9904129 A	28-04-2000
			JP 2000506500 T	30-05-2000
			NO 982738 A	21-08-1998
			PL 327567 A	21-12-1998
GB 2185887	A	05-08-1987	DE 3705074 A	01-09-1988
			CH 671881 A	13-10-1989
FR 2656303	A	28-06-1991	NONE	